REMARKS

Applicants thank the Examiner for the very thorough consideration given the present application.

Claims 1, 4-16, 23-28 and 36-423 are pending in this application. By this amendment, claim 43 is added. No new matter is involved. Claims 1, 23 and 43 are independent.

Reconsideration of this application, as amended, is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1, 4-16, 23-28 and 36-42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 97/26937 to Israelsson in view of the Bongard non-patent literature reference ("Bongard").

This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Because the rejection is based on 35 U.S.C. § 103, what is in issue in such a rejection is "the invention as a whole," not just a few features of the claimed invention. Under 35 U.S.C. § 103, "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under § 103 is whether the claimed invention *as a whole* would have been obvious to a person of ordinary skill in the art at the time the invention was made. *See In re O'Farrell*, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. *See Medtronic, Inc. v. Cardiac Pacemakers. Inc.*, 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. § 103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In doing so, the Examiner is expected to make the

factual determinations set forth in *Graham v John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *See Uniroyal Inc. v. F-Wiley Corp.,* 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), *cert. denied,* 488 U.S. 825 (1988); *Ashland Oil, Inc. v Delta Resins & Refactories, Inc.*, 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hospital Systems, Inc. v Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. *See In re Wilson,* 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *See C.R. Bard, Inc. v. M3 Sys. Inc.,* 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *See In re Dembiczak*, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Moreover, it is well settled that the Office must provide objective evidence of the basis used in a prior art rejection. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. *See In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Furthermore, during patent examination, the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the Applicants are entitled to the patent. Only when a *prima facie* case is made, the burden shifts to the Applicants to come forward to rebut such a case.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness:" *In re Kahn*, 441 F.3d 977,988(Fed. Cir. 2006) (quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

In the sentence just prior to citing the *Kahn* case, the U.S. Supreme Court clearly stated that there has to be an apparent reason to combine the known elements in the manner claimed. The Office has the burden of making out a *prima facie* case of obviousness, i.e., by presenting objective factual evidence of a reason to combine the known elements in the manner claimed. The *KSR* decision did not lift that burden from the Office.

The articulated reasoning has to express a rationale explaining what would have led an ordinarily skilled artisan to combine selected features from each reference in a way that would have resulted in the claimed invention. See, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Thus, the Supreme Court reaffirmed the fundamental principles set forth in the *Graham v. John Deere Co.* decision, cited and discussed above.

The two independent claims under rejection, as amended, recite an assembly in which the wetting fluid is stored separately.

The presently claimed invention provides a catheter assembly for hydrophilic urinary catheters, where the hydrophilic coatings have an improved stability during wetting (i.e., the resulting osmolality in the coating when wetted is less dependent on the wetting time) and exhibit lower friction (i.e., a lower extraction force is required) and improved water retention (i.e. an increase in the remaining wetting fluid content of the catheters after drying) than would have been expected *a priori*.

Seen from the perspective of the user, who is typically a disabled person confined to a wheel chair, initial friction has the positive consequence that insertion and withdrawal of the catheter is relatively easy and painless. Further, the high water retention (i.e. long drying time) has the consequence that a longer period is available for the user, both in terms of the handling time before insertion and the available time before it potentially becomes painful to remove the catheter after insertion. It should further be mentioned that catheters have a tendency to dry out at the insertion point (i.e., the boundary between free air and the urethra) and this may cause considerable pain when removing a catheter because it adheres to the mucous membrane at the urethral opening. Still further, the increased stability during wetting makes the wetting process less critical, and reduces problems related to a too short or a too long wetting period.

Altogether, the technical advantages obtained (low friction, long-time water retention and stability during wetting) provides for a catheter assembly which is more user friendly because it is easy to activate before use, easy to insert, permits a longer time for handling and does not have to be removed within a very short time after insertion. This also means that the technical advantages are highly relevant in the real-life situation where the catheter is used.

Thus, the objective of the present invention may be seen as the quest for a more user friendly urinary catheter assembly, and more specifically an assembly that solves three equally important technical problems: to provide a catheter assembly that 1) maintain/obtain reduced friction of the hydrophilic coating of the catheter, 2) have an improved stability during wetting and 3) maintains a wetted state (conserves slipperiness) for a prolonged period of time.

The solution provided by the present invention is to provide a wetting fluid for wetting of a hydrophilic surface layer on a catheter comprising a total concentration of at least one dissolved osmolality-increasing compound(s) exceeding 600 $mOsm/dm^3$.

Applicants respectfully submit that, based on the teachings of the prior art, this solution is far from obvious to one having ordinary skill in the art.

Because the patent reports and acknowledges the advantages of both prolonged wetted state AND the advantages of a reduced friction AND the increased stability during wetting, the skilled person would not combine Bongard with Israelsson in order to arrive at the claimed

subject matter because neither Bongard nor Israelsson points to anything remotely like the surprising findings of Tables 1-3 of the present application.

In Table 1 of the present application, a comparative experiment is discussed related to the importance of the concentration of the osmolality-increasing compound in the wetting liquid for the resulting friction of the catheter surface when wetted. As is clearly evident from the measurements illustrated in table 1, there is a dramatic improvement and decrease in the required extraction force when wetting fluids having an osmolality level of 700 mOsm/dm^3 or above is used, compared to when a level of 500 mOsm/dm^3 is used. This effect is clearly visible in both the catheter types used for the experiment.

By the present inventors, it has been found that an omsolality level of 600 mOsm/dm^3 or above leads to a dramatic improvement in terms of the friction on the catheter surface (as discussed in relation to Table 1 in the application).

In response to these previously presented arguments, the outstanding Office Action indicates that Applicants should present a showing under 37 CFR §132 to support these arguments.

Applicants understand the position of the Examiner in this regard. However, Applicants respectfully submit that support for Applicants' position in this regard is found in the Application, as originally filed. For example, in table 1 of the present application, a comparative experiment is discussed related to the importance of the concentration of the osmolality-increasing compound in the wetting liquid for the resulting friction of the catheter surface when wetted. As is clearly evident from the measurements illustrated in Table 1, there is a dramatic improvement and decrease in the required extraction force when wetting fluids having an osmolality level of 700 mOsm/dm^3 or above is used, compared to when a level of 500 mOsm/dm^3 is used. This effect is clearly visible in both the catheter types used for the experiment. This table clearly supports the dramatic improvements achieved by the present inventors that an osmolality level of 600 mOsm/dm^3 or above leads to a dramatic improvement in terms of the friction on the catheter surface (as discussed in relation to Table 1 in the application).

Additionally, Applicants respectfully submit that such a result is far from obvious in view also of Johansson, since it would not have been obvious what the resulting concentration of osmolality increasing compound in the wetted catheter coating would have been when using a certain osmolality level in the wetting fluid. Further, it would not have been obvious for the skilled addressee how long it would take (seconds, hours, weeks ...) to reach a certain concentration of osmolality increasing compound in the wetted catheter coating when a certain osmolality level in the wetting fluid was used. Thus, the skilled addressee would at the time, and based on the teachings from the cited art, not be able to foresee the resulting effect on the catheter coatings by using a wetting liquid with a certain osmolality level.

In Table 2 of the present application, a comparative experiment is discussed related to the stability of the wetting process for a catheter where the osmolality increasing compound is integrated in the coating compared to a catheter where the osmolality increasing compound is dissolved in the wetting liquid. **As is clearly evident from the measurements illustrated in Table 2, there is a dramatic improvement in stability in the catheter 2 in which the osmolality increasing compound is dissolved in the wetting fluid, compared to catheter 1 in which the osmolality increasing compound is incorporated in the hydrophilic coating.**

In Table 3 of the present application, a comparative experiment is discussed related to the water retention (wetting fluid content after drying) of a catheter where the osmolality increasing compound is integrated in the coating compared to a catheter where the osmolality increasing compound is dissolved in the wetting liquid. **As is clearly evident from the measurements illustrated in Table 3, the wetting fluid content in the catheters 2 are significantly higher than in the catheters 1, and the water retention in the catheters wetted by a wetting fluid in which the osmolality increasing compound is dissolved is apparently improved over the water retention in the catheters having a corresponding concentration of osmolality increasing compound in the coating.**

Additionally, Applicants respectfully submit that the aforementioned tables in their Application present a detailed factual basis on which to conclude that the claimed invention has achieved unexpected results.

The primary reference used in this rejection is Israelsson. Regarding Israelsson, Applicants respectfully note that even though it discloses a catheter assembly structurally similar to the presently claimed invention, and also mentions the possibility of using saline as a wetting fluid, it does not disclose including an osmolality increasing compound at the very high level of such a compound as positively recited in the claims. Moreover, Israelsson fails to disclose any specific advantages or reasons for using such a high concentration.

Applicants respectfully submit that the mentioning of "saline" in Israelsson is clearly directed to normal saline and not hypertonic saline.

Using Israelsson as a starting point, an objective technical problem may be seen as providing a catheter assembly which in the use situation has a very high osmolality, and which provides a lowered sensibility to variations in wetting time, and which maintains a wetted state (conserves slipperiness) for a longer period of time. There is no guidance in respect of this problem in any of the cited prior art documents.

In an attempt to remedy the shortcomings of Israelsson, the outstanding Office Action turns to Bongard. Bongard discusses so-called "hypertonic saline". By way of background, Applicants respectfully submit that one of ordinary skill in the art understands that normal saline is a solution of 0.90% w/v of NaCl, about 300 mOsm/L. Such normal saline may also be referred to as *physiological saline* or *isotonic saline*. Hypertonic saline may be used in perioperative fluid management protocols to reduce excessive intravenous fluid infusions and lessen pulmonary complications. Hypertonic saline is used in treating hyponatremia. However, rapid correction of hyponatremia via hypertonic saline, or via any saline infusion > 40 mmol/L (Na+ having a valence of 1, 40 mmol/L = 40 mEq/L) greatly increases risk of central pontine myelinolysis (CPM), and so requires constant monitoring of patient response. Moreover, due to hypertonicity, administration may result in phlebitis and tissue necrosis. As such, concentrations greater than 3% NaCl should normally be administered via a central venous catheter, also known as a 'central line'. (see e.g., Wikipedia: http://en.wikipedia.org/wiki/Saline_(medicine)).

Hyponatremia (Brit. Hyponatraemia) is an electrolyte disturbance in which the sodium concentration in the serum is lower than normal. In the vast majority of cases, hyponatremia occurs as a result of excess body water diluting the serum sodium and is not due to sodium

deficiency. Hyponatremia is most often a complication of other medical illnesses in which excess water accumulates in the body at a higher rate than can be excreted (for example in congestive heart failure, syndrome of inappropriate antidiuretic hormone, SIADH, or polydipsia). (See e.g., Wikipedia: http://en.wikipedia.org/wiki/Hyponatremia).

Thus, hypertonic saline is only used very rarely, for treatment of special illness conditions, and in particular hyponatremia, and under strong supervision. Applicants respectfully submit that this is also made clear from Bongard.

Applicants respectfully submit that none of the applied art contains a disclosure of this hypertonic saline as a wetting solution for a hydrophobic urinary catheter, and that one of ordinary skill in the art only has an appreciation of using hypertonic saline to treat special illness conditions, and in particular hyponatremia, and only under strong supervision. Thus, there is no reasonable basis in the applied art which would provide a proper incentive to one of ordinary skill in the art to arrive at, suggest, or otherwise render obvious the claimed invention.

In response to these previously presented arguments, the outstanding Office Action indicates that the Examiner believes that the saline disclosed by Israelsson is inclusive of normal and hypertonic saline, the two most likely types of saline that one of ordinary skill in the art would employ as an osmolality increasing compound to the surface of the catheter.

In support of this conclusion, Applicants respectfully submit that it is well known to one of ordinary skill in the art that saline of ordinary osmolality (i.e. 0.9 %) is widely used for most medical applications, whereas hypertonic saline is only used rarely, for very specific treatments, and under strict supervision. This is clear from Bongard itself. It would also be apparent from any literature on this subject. For example, it is mentioned in Wikipedia.org/wiki/Saline_(medicine) (emphasis added):

> **In medicine, saline (also saline solution) is a general phrase referring to a sterile solution of sodium chloride (NaCl, more commonly known as salt) in water but is only sterile when it is to be placed parenterally (such as intravenously), otherwise, a saline solution is a salt water solution. The sterile**

solution is typically used for intravenous infusion, rinsing contact lenses, nasal irrigation, and often used to clean a new piercing. Saline solutions are available in various formulations for different purposes. Salines are also used in cell biology, molecular biology, and biochemistry experiments.

Concentrations

Concentrations vary from low to normal to high. High concentrations are used rarely in medicine but frequently in molecular biology.

Normal

Normal saline (NS) is the commonly-used phrase for a solution of 0.90% w/v of NaCl, about 300 mOsm/L or 9.0 g per liter. Less commonly, this solution is referred to as physiological saline or isotonic saline, neither of which is technically accurate. NS is used frequently in intravenous drips (IVs) for patients who cannot take fluids orally and have developed or are in danger of developing dehydration or hypovolemia. NS is typically the first fluid used when hypovolemia is severe enough to threaten the adequacy of blood circulation, and has long been believed to be the safest fluid to give quickly in large volumes. However, it is now known that rapid infusion of NS can cause metabolic acidosis.[1]

...

Usage

For medical uses, saline is often used to flush wounds and skin abrasions. Normal saline will not burn or sting when applied.

Saline is also used in I.V. therapy, intravenously supplying extra water to a dehydrated patient or supplying the daily water and salt needs ("maintenance" needs) of a patient who is unable to take them by mouth. Because infusing a solution of low osmolality can cause problems, intravenous solutions with reduced saline concentrations typically have dextrose (glucose)

added to maintain a safe osmolality while providing less sodium chloride. As the molecular weight (MW) of dextrose is greater, this has the same osmolality as normal saline despite having less.

The amount of normal saline infused depends largely on the needs of the patient (e.g. ongoing diarrhea or heart failure) but is typically between 1.5 and 3 litres a day for an adult.

Rinse eye drops are often distributed for free by needle-exchange programmes. Containing normal saline, they are small, sterile, and safe for intravenous use.

Saline is also often used for nasal washes to relieve some of the symptoms of the common cold. In this case "home-made" saline may be used: this is made by dissolving approximately half a teaspoonful of table salt into a glass of clean tap water [citation needed]. At least two deaths have been reported from using unboiled or otherwise unsterilized tap water for nasal irrigation [citation needed].

Hypertonic saline

Hypertonic saline (NS) — 7% NaCl solutions are considered mucoactive agents and as such are used to hydrate thick secretions (mucous) in order to make it easier to cough up and out (expectorate). 3% hypertonic saline solutions are also used in critical care settings to help in haemorrhagic shock (but no other type of shock), acutely increased intracranial pressure, or severe hyponatremia.[4] Inhalation of hypertonic saline has also been shown to help in other respiratory problems, specifically bronchiolitis.[5] Hypertonic saline is currently recommended by the Cystic Fibrosis Foundation as a primary part of a cystic fibrosis treatment regimen.[6]

...

Thus, normal saline is well-known to be used for irrigation, eye cleaning, etc., and would be considered appropriate also for wetting a urinary catheter, whereas a hypertonic saline would not normally be considered for such use.

Further, the outstanding Office Action does not provide evidence that hyponatremia is treated by using different types of saline for urinary catheters. Thus, the outstanding Office Action does not establish on a *prima facie* basis that one of ordinary skill in the art would, as stated in the outstanding Office Action on p. 2, middle of the first paragraph, consider to use hypertonic saline for patients suffering from hyponatremia. Such a treatment is also not at all foreseen or advocated by Bongard.

Additionally, at the end of this paragraph (p. 2, first paragraph), the outstanding Office Action states that "*it would readily be understood by one of ordinary skill in the art that an individual using this catheter is not inserting it him or herself in the complete absence of trained health care personnel and is this already under "strong supervision", wherein any complications from the use of hypertonic saline can readily be reversed.*" This is simply wrong.

Applicants respectfully submit that, whereas indwelling, long term, catheters are often inserted by trained health care personnel, hydrophilic catheters for intermittent use (clearly the type disclosed by Israelsson, the primary references used in this rejection) are often handled (prepared, inserted and withdrawn) by the user himself. This self-catheterization is reflected in the Israelsson document (p. 1, lines 11-19 in Israelsson '937, for example).

In fact, the very purpose of providing a catheter assembly including a wetting liquid supply within the package is to enable for users to perform self-catheterization when outside a medical center, such as being in their homes or away on trips etc. In a medical center, and when handled by trained personnel, there is no need to have such assemblies,

since sterile water and sterile conditions are readily at hand anyway. Thus, these types of catheter assemblies which include a wetting liquid supply are predominantly used by users performing self-catheterization.

Another way of addressing the shortcomings of this rejection is to note that the present invention provides a catheter assembly for hydrophilic urinary catheters, where the hydrophilic coatings have an improved stability during wetting (i.e. the resulting osmolality in the coating when wetted is less dependent on the wetting time) and exhibit lower friction (i.e., a lower extraction force is required) and improved water retention (i.e. an increase in the remaining wetting fluid content of the catheters after drying) than would have been expected *a priori*.

Seen from the perspective of the user, who is typically a disabled person confined to a wheel chair, initial friction has the positive consequence that insertion and withdrawal of the catheter is relatively easy and painless. Further, the high water retention (i.e., long drying time) has the consequence that a longer period is available for the user, both in terms of the handling time before insertion and the available time before it potentially becomes painful to remove the catheter after insertion. It should further be mentioned that catheters have a tendency to dry out at the insertion point (i.e., the boundary between free air and the urethra) and this may cause considerable pain when removing a catheter because it adheres to the mucous membrane at the urethral opening. Still further, the increased stability during wetting makes the wetting process less critical, and reduces problems related to a too short or a too long wetting period.

Altogether, the technical advantages obtained (low friction, long-time water retention and stability during wetting) provides for a catheter assembly which is more user friendly because it is easy to activate before use, easy to insert, permits a longer time for handling and does not have to be removed within a very short time after insertion. This also means that the technical advantages are highly relevant in the real-life situation where the catheter is used.

Thus, the objective of the present invention may be seen as the quest for a more user friendly urinary catheter assembly, and more specifically an assembly that solves three equally important technical problems: to provide a catheter assembly that 1) maintain/obtain reduced

friction of the hydrophilic coating of the catheter, 2) have an improved stability during wetting and 3) maintains a wetted state (conserves slipperiness) for a prolonged period of time.

The solution provided by the present invention is to provide a wetting fluid for wetting of a hydrophilic surface layer on a catheter comprising a total concentration of at least one dissolved osmolality-increasing compound(s) exceeding 600 mOsm/dm^3. In view of the teachings of the prior art, this solution is far from obvious to the skilled person.

One having ordinary skill in the art would not combine Bongard with Israelsson in order to arrive at the claimed subject matter because neither Bongard nor Israelsson points to anything remotely like the aforementioned surprising findings of Tables 1-3 of the present application which disclose the advantages of both prolonged wetted state AND the advantages of a reduced friction AND the increased stability during wetting.

There is nothing in the cited prior art that points in the direction of the findings of the present invention, namely that advantages in terms of both prolonged wetted state and reduced friction and stability during wetting can be obtained when adding a water soluble compound of a certain concentration to the wetting liquid for a hydrophilic coated catheter. As shown above, surprisingly the use of a wetting liquid with a concentration of dissolved osmolality increasing compound(s) exceeding 600 mOsm/dm^3 leads to a catheter assembly that is superior to the comparative examples. This unexpected result could not be predicted and is neither taught nor suggested by any of the cited references.

It has been realized by the inventors that a very high level of osmolality is very advantageous for obtaining a low friction. As is demonstrated by the experiments discussed in relation to Table 1 (p. 18) there is a significant difference even when the osmolality increasing level is lowered to 500 mOsm/m^3 – a level which is per se considered to be a high level of osmolality, and significantly exceeding the osmolality level of e.g. physiological saline.

However, when using such high levels of osmolality, it has been found by the present inventors that wetting time significantly affects not only the resulting osmolality increasing fluid (see the experiments discussed in relation to Table 2, p. 19), but also the resulting water retention capabilities of the catheters (see the experiments discussed in relation to Table 3, p. 20).

For the foregoing reasons, Applicants respectfully submit that the Office Action fails to make out a *prima facie* case of obviousness of the claimed invention.

Thus, reconsideration and withdrawal of these two rejections under 35 USC §103(a) are respectfully requested.

New Claim 43

Claim 43 is an independent claim which recites a combination of features similar to those recited in claim 1, which are not disclosed or suggested by the applied art, for reasons presented above. Also, claim 43 recites a specific water retention feature which is neither disclosed, nor suggested, nor otherwise rendered obvious by the applied art.

Accordingly, consideration and allowance of claim 43 are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

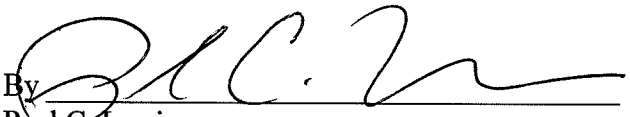
If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46, 472, at (703) 205-8000, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: March 6, 2012

Respectfully submitted,



By
Paul C. Lewis
Registration No. 43,368
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, VA 23040-0747
(703) 205-8000

Attachment: Request for Interview